

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	09/762,587	Group Art Unit:	1642
Confirmation No.:	5272	Examiner:	M.T. Davis
Filed (§ 371):	06 September 2001		
Applicant:	Antonio J. GRILLO-LÓPEZ		
For:	Use of Radiolabeled Anti-CD20 Antibody to Treat Rituximab-Refractory B-Cell Lymphoma (as amended)		

Mail Stop **Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the requirements and provisions of 37 C.F.R. §§ 1.56, 1.97, and 1.98, applicant cites the information listed on the Form PTO-1449 that accompanies this paper and the pending patent applications identified below. Applicant does not represent that a search has been conducted or that the cited documents are prior art against the claims in this application. Copies of the cited non-U.S. patent documents accompany this submission.

This disclosure statement is filed under the provisions of 37 C.F.R. § 1.97(c)(2) prior to the mailing date of a final action on the merits. Applicant requests that the Director charge the required fee (§ 1.17(p)) of **\$180**, as well as any other fees as may be required for consideration of this paper, to our **Deposit Account No. 18-1260**.

Copending patent applications

In addition to the information cited on the Form PTO-1449 that accompanies this paper, applicant directs the examiner's attention to the commonly-owned pending U.S. patent applications listed below.

Serial No.	Filing Date	First Inventor
09/436,347	09 Nov 1999	White
09/628,187	28 Jul 2000	White
09/911,692	25 Jul 2001	Anderson
09/911,703	25 Jul 2001	Anderson
10/196,732	17 Jul 2002	Grillo-López
10/238,681	11 Sep 2002	Anderson
10/440,186	19 May 2003	Grillo-López
10/850,712	21 May 2004	Grillo-López

Respectfully submitted,

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INFORMATION DISCLOSURE STATEMENT	Docket No.	27693-01186	Serial No:	09/ 762,587
	Inventor(s):	A.J. GRILLO-LÓPEZ	Examiner:	M.T. DAVIS
	Filed:	06 September 2001	Art Unit:	1642

U.S. PATENT DOCUMENTS

INITIAL	INDEX	DOCUMENT	DATE	NAME	CLASS	SUB.	FILING DATE
	D1	Re 38,008	25 Feb 2003	Abrams			
	D2	4,975,278	4 Dec 1990	Senter			
	D3	5,439,665	8 Aug 1995	Hansen			
	D4	5,595,721	21 Jan 1997	Kaminski			
	D5	5,648,267	15 Jul 1997	Reff			
	D6	5,677,171	14 Oct 1997	Hudziak			
	D7	5,686,072	11 Nov 1997	Uhr			
	D8	5,691,320	25 Nov 1997	van Borstel			
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	D11	5,399,061	1 Dec 1998	Anderson			
	D12	6,682,734 B1	27 Jan 2004	Anderson			
	D13	6,893,625 B1	17 May 2005	Robinson			
	D14	2002/ 0009444 A1	24 Jan 2002	Grillo-López			
	D15	2002/ 0197255 A1	26 Dec 2002	Anderson			
	D16	2003/ 0021781 A1	30 Jan 2003	Anderson			
	D17	2003/ 0026804 A1	24 Feb 2003	Grillo-López			
	D18	2003/ 0082172 A1	1 May 2003	Anderson			
	D19	2003/ 0095963 A1	22 May 2003	Anderson			
	D20	2003/ 0206903 A1	6 Nov 2003	Grillo-López			
	D21	2004/ 0167319 A1	26 Aug 2004	Teeling			
	D22	2004/ 0213784 A1	28 Oct 2004	Grillo-López			

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Form PTO-1449 (modified)	

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INITIAL	INDEX	DOCUMENT	DATE	NAME	CLASS	SUB.	FILING DATE
	D23	2005/ 0163708 A1	28 July 2005	Robinson			
	D24	2005/ 0186205 A1	25 Aug 2005	Anderson			
	D25	2006/ 0034835 A1	16 Feb 2006	Adams			

FOREIGN PATENT DOCUMENTS

INITIAL	INDEX	DOCUMENT	DATE	COUNTRY	CLASS	SUB.	TRANSLATION	
	D26	0 125 023 A1	14 Nov 1994	EP				
	D27	0 173 494 A2	5 May 1986	EP				
	D28	0 274 394 A2	13 Jul 1988	EP				
	D29	0 451 216 B1	24 Jan 1996	EP				
	D30	0 669 836 B1	7 Mar 1996	EP				
	D31	0 510 949 A2	28 Oct 1992	EP				
	D32	0 682 040 A1	15 Nov 1995	EP				
	D33	0 752 248 A1	8 Jan 1997	EP				
	D34	91/ 04320 A1	4 Apr 1991	WO				
	D35	92/ 07466 A1	14 May 1992	WO				
	D36	93/ 02108 A1	4 Feb 1993	WO				
	D37	94/11026 A2	26 May 1994	WO				
	D38	00/ 09160 A1	24 Feb 2000	WO				
	D39	00/ 27428 A1	18 May 2000	WO				
	D40	00/ 27433 A1	18 May 2000	WO				
	D41	01/ 10460 A1	15 Feb 2001	WO				
	D42	2004/ 056312 A2	8 Jul 2004	WO				

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OTHER DOCUMENTS

INITIAL	INDEX	CITATION
	D43	Adams R.A. <i>Cancer Res.</i> 27: 2479-82, 1967. Formal discussion: the role of transplantation in the experimental investigation of human leukemia and lymphoma.
	D44	Adams R.A. et al. <i>Cancer Res.</i> 28(6): 1121-25, 1968. Direct implantation and serial transplantation of human acute lymphoblastic leukemia in hamsters, SB-2.
	D45	Almasri N.M. et al. <i>Am. J. Hematol.</i> 40: 259-63, 1992. Reduced expression of CD20 antigen as a characteristic marker for chronic lymphocytic leukemia.
	D46	Anderson D.R. et al. Second IBC Int'l. Conference on Antibody Engineering, San Diego, 16-18 December 1991. Immunoreactivity and effector function associated with a chimeric anti-CD20 antibody (abstract of presentation).
	D47	Anderson K.C. et al. <i>Blood</i> 63(6): 1424-33, 1984. Expression of human B cell-associated antigens on leukemias and lymphomas: a model of human B cell differentiation.
	D48	Appelbaum F.R. <i>Hem. Onc. Clin. N. Amer.</i> 5(5): 1013-25, 1991. Radiolabeled monoclonal antibodies in the treatment of non-Hodgkin's lymphoma.
	D49	Armitage J.O. et al. <i>Cancer</i> 50: 1695-1702, 1982. Predicting therapeutic outcome in patients with diffuse histiocytic lymphoma treated with cyclophosphamide, adriamycin, vincristine and prednisone (CHOP).
	D50	Armitage J.O. et al. <i>J. Clin. Oncol.</i> 16(8): 2780-95, 1998. New approach to classifying non-Hodgkin's lymphomas: clinical features of the major histologic subtypes. Non-Hodgkin's Lymphoma Classification Project.
	D51	Badger C.C. et al. <i>Cancer Res.</i> 46: 6223-28, 1986. Experimental radioimmunotherapy of murine lymphoma with ¹³¹ I-labeled anti-T-cell antibodies.
	D52	Beychok S. (in) <i>Cells of Immunoglobulin Synthesis</i> , B. Pernis et al., eds. New York: Academic Press, 1979, 69-88. Comparative aspects of <i>in vitro</i> and cellular assembly of immunoglobulins.
	D53	Bhan A.K. et al. <i>J. Exp. Med.</i> 154: 737-49, 1981. Stages of B cell differentiation in human lymphoid tissue.
	D54	<i>Biogen Idec Inc. v. Corixa Corp.</i> , Case No. 01-CV-1637 IEG (RBB), Stipulation of Dismissal of Claims and Counterclaims with Prejudice and Order (S.D.Cal., May 13, 2004).

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INITIAL	INDEX	CITATION
	D55	Boulianne G.L. et al. <i>Nature</i> 312: 643-46, 1984. Production of functional chimaeric mouse/human antibody.
	D56	Brunner K.T. et al. <i>Immunology</i> 14(2): 181-96, 1968. Quantitative assay of the lytic action of immune lymphoid cells on ⁵¹ Cr-labelled allogeneic target cells in vitro; inhibition by isoantibody and by drugs.
	D57	Buchsbaum D.J. et al. <i>Cancer Res.</i> 50: 993s-999s, 1990. Comparative binding and preclinical localization and therapy studies with radiolabeled human chimeric and murine 17-1A monoclonal antibodies.
	D58	Buchsbaum D.J. et al. <i>Cancer Res.</i> 52: 637-642, 1992. Improved delivery of radiolabeled anti-B1 monoclonal antibody to Raji lymphoma xenografts by predosing with unlabeled anti-B1 monoclonal antibody.
	D59	Buchsbaum D.J. et al. <i>Cancer Res.</i> 52: 6476-81, 1992. Therapy with unlabeled and ¹³¹ I-labeled pan-B-cell monoclonal antibodies in nude mice bearing Raji Burkitt's lymphoma xenografts.
	D60	Buchsbaum D.J. et al. <i>I.J. Rad. Oncol. Biol. Phys.</i> 18: 1033-41, 1990. A comparison of ¹³¹ I-labeled monoclonal antibody 17-1A treatment to external beam irradiation on the growth of LS174T human colon carcinoma xenografts.
	D61	Buchsbaum D.J. et al. <i>I.J. Rad. Oncol. Biol. Phys.</i> 25(4): 629-38, 1993. Comparison of ¹³¹ I- and ⁹⁰ Y-labeled monoclonal antibody 17-1A for treatment of human colon cancer xenografts.
	D62	Byrd J.C. <i>Cancer Biother. Radiopharm.</i> 14(4)I. 323, 1999. Rituximab therapy in patients with chronic lymphocytic leukemia.
	D63	Byrd J.C. et al. <i>J. Clin. Oncol.</i> 17(3): 791-795, Mar. 1999. Rituximab therapy in hematologic malignancy patients with circulating blood tumor cells: association with increased infusion-related side effects and rapid blood tumor clearance.
	D64	Calvert J.E. et al. <i>Semin. Hematol.</i> 21(4): 226-243, 1984. Cellular events in the differentiation of antibody-secreting cells.
	D65	Carrasquillo J.A. et al. <i>J. Nucl. Med.</i> 26: 67, abst. no. 276, 1985. Improved imaging of metastatic melanoma with high dose 9.2.27 In-111 monoclonal antibody.
	D66	Chen J.J. et al. <i>J. Immunol.</i> 143(3): 1053-57, 1989. Tumor idiotype vaccines. VI. Synergistic anti-tumor effects with combined "internal image" anti-idiotypes and chemotherapy.

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INITIAL	INDEX	CITATION
	D67	Chinn P. et al. <i>Proc. Ann. Mtg. Am. Assn. Cancer Res.</i> 33: 337, abst. no. 2012, 1992. Production and characterization of radiolabeled anti-CD20 monoclonal antibody: potential application to treatment of B-cell lymphoma.
	D68	Chomczynski P. et al. <i>Anal. Biochem.</i> 162: 156-59, 1987. Single-step method of RNA isolation by acid guanidinium thiocyanate-phenol-chloroform extraction.
	D69	Clark E.A. et al. <i>J. Cell. Biochem.</i> (Suppl. 9A): 63, 1985. Anti-Bp35 antibody induces human B cell proliferation: implications for <i>in vivo</i> immunotherapy.
	D70	Clark E.A. et al. <i>Proc. Natl. Acad. Sci. USA</i> 82(6): 1766-70, 1985. Role of the Bp35 cell surface polypeptide in human B-cell activation.
	D71	Classon B.J. et al. <i>J. Exp. Med.</i> 169(4): 1497-1502, 1989. The primary structure of the human leukocyte antigen CD37, a species homologue of the rat MRC OC-44 antigen.
	D72	Cogliatti S.B. et al. <i>Sw. Med. Weekly</i> 192: 607-17, 2002. Who is <i>WHO</i> and what was <i>REAL</i> ?
	D73	Coiffier B. <i>Ann. Oncol.</i> 83(Suppl 1): S73-S74, 2004. New treatment strategies in lymphomas: aggressive lymphomas.
	D74	Coiffier B. et al. <i>N. Engl. J. Med.</i> 346(4): 235-42, 2002. CHOP chemotherapy plus rituximab compared with CHOP alone in elderly patients with diffuse large-B-cell lymphoma.
	D75	Coleman M. et al. <i>Blood</i> 102(11 pt.1): 29a, abst. no. 29, 2003. The BEXXAR® therapeutic regimen (tositumomab and Iodine I-131 tositumomab) produced durable complete remissions in heavily pretreated patients with non-Hodgkin's lymphoma (NHL), rituximab-relapsed/refractory disease, and rituximab-naïve disease.
	D76	Cope. <i>Oncology</i> 8(4): 100, 1994. Antibody shows promise in treating B-cell lymphoma.
	D77	Davis T.A. et al. <i>Blood</i> 92(10 Suppl. 1): 414a, abst. no. 1711, Nov. 1998. Rituximab: first report of a phase II (PII) trial in NHL patients (PTS) with bulky disease.
	D78	DeNardo G.L. et al. <i>Cancer Res.</i> 50(3 Suppl.): 1014s-1016s, 1990. Fractionated radioimmunotherapy of B-cell malignancies with ¹³¹ I-Lym-1.
	D79	DeNardo G.L. et al. <i>I.J. Rad. Oncol. Biol. Phys.</i> 11(2): 335-48, 1985. Requirements for a treatment plan in system for radioimmunotherapy.
	D80	DeNardo S.J. et al. <i>Antibody Immunoconj. Radiopharm.</i> 1(1): 17-33, 1988. Pilot studies of radioimmunotherapy of B cell lymphoma and leukemia using I-131 Lym-1 monoclonal antibody.
	D81	DeNardo S.J. et al. <i>Cancer</i> 73(3 Suppl.): 1023-32, 1994. The biologic window for chimeric L6 radioimmunotherapy.

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INITIAL	INDEX	CITATION
	D82	Dickson S. <i>Gen. Engr. News</i> 5(3): 1, March 1985. Scientists produce chimeric monoclonal Abs.
	D83	Eary J.F. et al. <i>J. Nuc. Med.</i> 31(8): 1257-68, 1990. Imaging and treatment of B-cell lymphoma.
	D84	Einfeld D.A. et al. <i>EMBO J.</i> 7: 711-17, 1988. Molecular cloning of the human B cell CD20 receptor predicts a hydrophobic protein with multiple transmembrane domains.
	D85	Ford et al. <i>Highlights in Oncology Practice</i> 16(2): 40-50, 1998. Immunotherapeutic approaches to treatment of B-cell neoplasms: focus on unconjugated antibodies.
	D86	Freedman A.S. et al. <i>J. Clin. Oncol.</i> 8: 784-91, 1990. Autologous bone marrow transplantation in B-cell non-Hodgkin's lymphoma: very low treatment-related mortality in 100 patients in sensitive relapse.
	D87	Friedberg J.W. et al. <i>Expert Rev. Anticancer Ther.</i> 4(1): 18-26, 2004. Iodine-131 tositumomab (Bexxar®): radioimmunoconjugate therapy for indolent and transformed B-cell non-Hodgkin's lymphoma.
	D88	Golay J.T. et al. <i>J. Immunol.</i> 135(6): 3795-801, 1985. The CD20 (Bp35) antigen is involved in activation of B cells from the G0 to the G1 phase of the cell cycle.
	D89	Goldenberg D.M. et al. <i>J. Clin. Oncol.</i> 9(4): 548-64, 1991. Imaging and therapy of gastrointestinal cancers with radiolabeled antibodies.
	D90	Greenberger J.S. et al. <i>Cancer Res.</i> 45(2): 758-67, 1985. Effects of monoclonal antibody and complement treatment of human marrow on hematopoiesis in continuous bone marrow culture.
	D91	Grillo-López A.J. et al. <i>Br. J. Haematol.</i> 93(Suppl. 2): 283, abst. no. 1072, 1996. IDEC-C2B8 chimeric anti-CD20 antibody (MAB): safety and clinical activity in the treatment of patients (PTS) with relapsed low-grade or follicular (IWF:A-D) non-Hodgkin's lymphoma (NHL).
	D92	Harris N.L. et al. <i>Blood</i> 54(5): 1361-92, 1994. A revised European-American classification of lymphoid neoplasms: a proposal from the International Lymphoma Study Group.
	D93	Harris N.L. et al. <i>J. Clin. Oncol.</i> 17(12): 3835-49, 1999. World Health Organization classification of neoplastic diseases of the hematopoietic and lymphoid tissues: report of the Clinical Advisory Committee meeting—Airlie House, Virginia, November 1997.
	D94	Hekman A. et al. <i>Ann. Rept. Netherlands Cancer Inst., Amsterdam</i> , pages 47-48, 1993. Immunotherapy.

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INITIAL	INDEX	CITATION
	D95	Herold M. et al. <i>Ann. Hematol.</i> 79: 332-335, 2000. Successful treatment and re-treatment of resistant B-cell chronic lymphocytic leukemia with the monoclonal anti-CD20 antibody rituximab.
	D96	Hiddeemann W. et al. <i>Blood</i> 88(11): 4085-89, 1996. Lymphoma classification—the gap between biology and clinical management is closing.
	D97	Hooijberg E. et al. <i>Cancer Res.</i> 55: 2627-34, 1995. Eradication of large human B cell tumors in nude mice with unconjugated CD20 monoclonal antibodies and interleukin 2.
	D98	IDEC Pharmaceuticals Corp. and Genentech, Inc., Product insert for RITUXAN® approved by U.S. Food and Drug Administration on 26 November 1997.
	D99	IDEC Pharmaceuticals Corp., U.S. Securities and Exchange Commission Form S-1 Registration Statement, 1991.
	D100	Juwaid M. et al. <i>Cancer Res.</i> 55(23 Suppl.): 5827s-5831s, 1995. Estimates of red marrow dose by sacral scintigraphy in radioimmunotherapy patients having non-Hodgkin's lymphoma and diffuse bone marrow uptake.
	D101	Kaminski M.S. et al. <i>Antibody Immunoconj. Radiopharm.</i> 5(3): 345, abst. no. 57, 1992. Initial clinical radioimmunotherapy results with ¹³¹ I-anti-B1 (anti-CD20) in refractory B-cell lymphoma.”
	D102	Kaminski M.S. et al. <i>Blood</i> 78(10 Suppl. 1): 43a, abst. no. 161, 1992. Radioimmunotherapy (RIT) of refractory B-cell lymphoma with ¹³¹ I-anti-B1 (anti-CD20) antibody: promising early results using non-marrow ablative radiation doses.
	D103	Kaminski M.S. et al. <i>N. Engl. J. Med.</i> 329: 459-65, 1993. Radioimmunotherapy of B-cell lymphoma with [¹³¹ I]anti-B1 (anti-CD20) antibody.
	D104	Kinoshita T. et al. <i>J. Clin. Oncol.</i> 16(12): 3916, Dec. 1998. CD20-negative relapse in B-cell lymphoma after treatment with Rituximab.
	D105	Langmuir V.K. <i>Nucl. Med. Biol.</i> 19(2): 213-55, 1992. Radioimmunotherapy: clinical results and dosimetric considerations.
	D106	Larson S.M. et al. <i>Nucl. Med. Biol.</i> 16: 153-58, 1989. Comparison of bone marrow dosimetry and toxic effect of high dose ¹³¹ I-labeled monoclonal antibodies administered to man.
	D107	Leichner P.K. et al. <i>Front. Rad. Ther. Oncol.</i> 24: 109-20, 1990. Dosimetry and treatment planning in radioimmunotherapy.
	D108	Leichner P.K. et al. <i>Med. Phys.</i> 20(2): 529-34, 1993. Tumor dosimetry in radioimmunotherapy: methods of calculation for beta particles.

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	D109	Levy R. et al. <i>Fed. Proc.</i> 42: 2650-56, 1983. Tumor therapy with monoclonal antibodies.
	D110	Ling N.R. et al. (in) <i>Leucocyte Typing III: White Cell Differentiation Antigens</i> , A.J. McMichael et al., eds., Oxford: Oxford Univ. Pr., 1987, pp. 302-35. B-cell and plasma cell antigens: new and previously defined clusters.
	D111	Link M.P. et al. <i>J. Immunol.</i> 137(9): 3013-18, 1986. A unique antigen on mature B-cells defined by a monoclonal antibody.
	D112	Lipton J.M. et al. <i>Blood</i> 60(5 Suppl. 1): 170a, abst. no. 609, 1992. Distribution of B1, CALLA, β 2 microglobulin and Ia on hematopoiesis supporting cells (HSC) in short and long-term cultures.
	D113	Liu A.Y. et al. <i>J. Immunol.</i> 139(10): 3521-26, Nov. 1987. Production of a mouse-human chimeric monoclonal antibody to CD20 with potent Fc-dependent biologic activity.
	D114	Lonberg N. et al. <i>Nature</i> 368: 856-59, 1994. Antigen-specific human antibodies from mice comprising four distinct genetic modifications
	D115	Lowman H.B. Slides presented at IBC Antibody Engineering Conference, 2 December 2003. Differential activities in a series of humanized anti-CD20 antibodies.
	D116	Macey D.J. et al. <i>Front. Rad. Ther. Oncol.</i> 24: 123-31, 1990. A treatment planning program for radioimmunotherapy.
	D117	Macklis R.M. et al. <i>Antibody Immunoconj. Radiother.</i> 5(3): asbst. no. 39, 1992. Induction of programmed cell death in malignant lymphomas after radioimmunotherapy.
	D118	Macklis R.M. et al. <i>Cancer</i> 73(3 Suppl.): 966-73, 1994. Radiobiologic studies of low-dose-rate ^{90}Y -lymphoma therapy.
	D119	Maloney D.G. et al. <i>Blood</i> 80(6): 1502-1510, 1992. Monoclonal anti-idiotypic antibody therapy of B-cell lymphoma: the addition of a short course of chemotherapy does not interfere with the antitumor effect nor prevent the emergence of idiotype-negative variant cells.
	D120	Maloney D.G. et al. <i>Blood</i> 88(10: Suppl. 1): 637a, abst. no. 2635, 1996. The anti-tumor effect of monoclonal anti-CD20 antibody (mAb) therapy includes direct anti-proliferative activity and induction of apoptosis in CD20 positive non-Hodgkin's lymphoma (NHL) cell lines.
	D121	Mariuzza et al. <i>Science</i> . 233: 747-753, 1986. Three-dimensional structure of an antigen-antibody complex at 2.8 Å resolution.
	D122	Marx J.L. <i>Science</i> 229(4712): 455-56, 1985. Antibodies made to order.

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	D123	Masucci G. et al. <i>Med. Oncol. Tumor Pharmacother.</i> 8(3): 207-20, 1991. Chemotherapy and immunotherapy of colorectal cancer.
	D124	McLaughlin P. et al. <i>Oncology</i> 12(12): 1763-81, 1998. Clinical status and optimal use of rituximab for B-cell lymphomas.
	D125	Meredith R.F. et al. <i>J. Nucl. Med.</i> 33(9): 1648-53, 1992. Dose fractionation of radiolabeled antibodies in patients with metastatic colon cancer.
	D126	Mishell B.E. et al., eds. <i>Selected Methods in Cellular Immunology</i> , San Francisco: Freeman (1980), p. 287-304. Modification and use of antibodies to label cell surface antigens.
	D127	Morrison S. et al. <i>Proc. Nat'l Acad. Sci. USA</i> 81: 6851-54, 1984. Chimeric human antibody molecules: mouse antigen-binding domains with human constant region domains.
	D128	Morrison S.L. <i>Science</i> 229: 1202-07, 1985. Transfectomas provide novel chimeric antibodies.
	D129	Multani P.S. et al. <i>J. Clin. Oncol.</i> 16(11): 3691-3710, 1998. Monoclonal antibody-based therapies for hematologic malignancies.
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